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October 7, 1992

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Attn: Section 8(e) Coordinator (CAP Agreement)

Re: CAP Agreement Identification No. 8ECAP-0110

Dear Sir or Madam:

Union Carbide Corporation ("Union Carbide") herewith submits the following report pursuant to the terms of the TSCA §8(e) Compliance Audit Program and Union Carbide's CAP Agreement dated August 14, 1991 (8ECAP-0110). This report describes an environmental toxicity study (Daphnia Magna) with UC 54012 25WP (N-[[[(4-chlorophenyl)amino]-carbonyl]-2,6-difluorobenzamide; CASRN 35367-38-5.

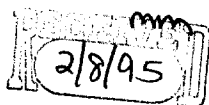
"Acute Toxicity of uC 54012 25 WP to Daphnia magna", Analytical Bio-Chemistry Laboratories, Inc., Static Acute Toxicity Report No. 34978, August 27, 1986.

A complete summary of this report is attached.

Previous TSCA Section 8(e) or "FYI" Submission(s) related to this substance are:

(None)

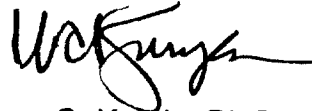
Previous PMN submissions related to this substance are: (None)



This information is submitted in light of EPA's current guidance. Union Carbide does not necessarily agree that this information reasonably supports the conclusion that the subject chemical presents a substantial risk of injury to health or the environment.

In the attached report the term "CONFIDENTIAL" may appear. This precautionary statement was for internal use at the time of issuance of the report. Confidentiality is hereby waived for purposes of the needs of the Agency in assessing health and safety information. The Agency is advised, however, that the publication rights to the contained information are the property of Union Carbide.

Yours truly,



William C. Kuryla, Ph.D.
Associate Director
Product Safety
(203/794-5230)

WCK/cr

Attachment (3 copies of cover letter, summary, and report)

SUMMARY

BEST COPY AVAILABLE



ANALYTICAL BIOCHEMISTRY LABORATORIES, INC.
P.O. Box 1097 • Columbia, MO 65201
Shipping Address: 7200 East ABC Lane, Columbia, MO 65202
(314) 474-8579 • Telex 821 814 • Cablegrams: ABC

Static Acute Toxicity Report
#34978

Acute Toxicity of UC 54012 25WP
to Daphnia magna

Submitted To:

Union Carbide Agricultural Products Company, Inc.
Attn: Dr. Thomas L. Merriam
P.O. Box 12014, T. W. Alexander Drive
Research Triangle Park, North Carolina 27709

August 27, 1986

SUMMARY

(4)

RESULTS

Table 2 presents the predicted LC_{50} values and 95-percent confidence intervals for UC 54012 25WP. The 24- and 48-hour LC_{50} values for UC 54012 25WP were 0.99 and 0.26 mg/l. All results were based on the nominal concentrations of 0.10, 0.18, 0.32, 0.56, 1.0, 1.8 and 32 μ g/l. The no-effect concentration based on the lack of mortality and abnormal effects was 0.10 μ g/l after 48 hours. The abnormal effects of mortality, quiescence, surfacing, erratic locomotion and/or daphnids lying on the bottom of test vessels were observed in the 0.18, 0.32, 0.56, 1.0, 1.8 and 32 μ g/l test concentrations.

Table 3 presents the mortality rate and water quality parameters measured during the test. The dissolved oxygen concentrations ranged between 8.4 and 8.6 mg/l. These values represented 91 and 93-percent saturation at 20°C, respectively, and were considered adequate for testing (1). The pH values of the treated chambers were consistent with the control and ranged from 8.1 to 8.2.

The study was conducted following the intent of the Good Laboratory Practice Regulations (5) and the final report was reviewed by Analytical Bio-Chemistry Laboratories' Quality Assurance Unit. All original raw data were provided to Union Carbide Agricultural Products Company, Inc., with a copy retained at Analytical Bio-Chemistry Laboratories.



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072-01-10-112

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Static Acute Toxicity Report
#34978

Acute Toxicity of UC 54012 25WP
to Daphnia magna

Submitted To:

Union Carbide Agricultural Products Company, Inc.
Attn: Dr. Thomas L. Merriam
P.O. Box 12014, T. W. Alexander Drive
Research Triangle Park, North Carolina 27709

August 27, 1986

BEST COPY AVAILABLE

Submitted By: Analytical Bio-Chemistry Laboratories, Inc.
7200 East ABC Lane
P. O. Box 1097
Columbia, Missouri 65205
(314) 474-8579

Prepared By:

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Lee T. Schoen 8/28/86
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Approved By:

Alan D. Forbis 8/28/86
Alan D. Forbis Date
Study Director/
Supervisor, Invertebrate and
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Phillip M. Buckler 8-28-86
Phillip M. Buckler Date
Quality Assurance Supervisor

Carl M. Thompson 8-28-86
Carl M. Thompson Date
Aquatic Toxicology Manager

/lrm

TABLE OF CONTENTS

	<u>Page No.</u>
LIST OF ILLUSTRATIONS.	34978-iv
SUMMARY.	34978-1
INTRODUCTION	34978-2
METHODS AND MATERIALS.	34978-2
RESULTS.	34978-3
LITERATURE CITED	34978-7
QUALITY ASSURANCE STATEMENT.	34978-8
STUDY COMPLIANCE STATEMENT	34978-9
APPENDIX - RAW DATA.	34978-10

LIST OF ILLUSTRATIONS

<u>Table No.</u>		<u>Page No.</u>
1	Chemical Characteristics of Well Water Used by ABC's Aquatic Toxicology Division.34978-4
2	Acute Toxicity of UC 54012 25WP to <u>Daphnia magna</u> . .	.34978-5
3	Mortality Rates and Water Quality Measurements During the Acute Toxicity Test of UC 54012 25WP to <u>Daphnia magna</u>34978-6

SUMMARY

The acute toxicity of UC 54012 25WP to Daphnia magna was assessed using the methods outlined by the Committee on Methods for Toxicity Tests with Aquatic Organisms. Water quality parameters of temperature, dissolved oxygen and pH were measured at the termination of the test and were within acceptable limits.

The results of the 48-hour static Daphnia magna toxicity study are summarized below. All reported values were based upon nominal concentrations.

<u>Compound</u>	<u>48-hour LC₅₀ (95% C.I.)</u>
UC 54012 25WP	0.26 µg/l (0.21-0.31 µg/l)

The no-effect level observed for UC 54012 25WP was 0.10 µg/l after 48 hours, since mortality and abnormal effects occurred at all test concentrations.

INTRODUCTION

This definitive static bioassay was performed by the Aquatic Toxicology Division of Analytical Bio-Chemistry Laboratories, Inc., Columbia, Missouri, for Union Carbide Agricultural Products Company, Inc., from August 18, 1986 to August 20, 1986. The purpose of this test was to determine the 24- and 48-hour LC_{50} levels for UC 54012 25WP to Daphnia magna. The study was performed using ABC Protocol #7806 as approved by Dr. Thomas L. Merriam, Union Carbide Agricultural Products Company, Inc. on July 29, 1986.

METHODS AND MATERIALS

The procedures for static bioassay, as described in Methods of Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians (1) and Standard Methods for Examination of Water and Wastewater (2), were used in this experiment. The Daphnia magna used in the test were cultured at the ABC facilities. The adult Daphnia were fed algae (Selenastrum capricornutum) at least every three days prior to testing and supplemented with a suspension of fish food. The daphnids were identified to species using the taxonomic key presented by Pennak (3).

The static Daphnia bioassay was conducted in 250-ml glass beakers containing 200 ml of ABC aged well water with the chemical characteristics listed in Table 1. These vessels were kept at 20 (± 2.0) °C in a temperature controlled area. The lighting was maintained at 50-70 foot-candles on a 16-hour daylight photoperiod with 30-minute simulated dawn and dusk periods.

Initial range-finding experiments were conducted using 10 Daphnia each in exposure concentrations of 0.010, 0.10 and 1.0 $\mu\text{g/l}$, 0.0010, 0.010, 0.10, 1.0, and 0.10, 1.0, 10 and 100 mg/l . From this information, seven concentrations in duplicate of the test compound with ten Daphnia (first instar less than 24 hours old) per beaker were selected for the definitive bioassay. These concentrations were a logarithmic series ranging from 0.10 to 3.2 $\mu\text{g/l}$ and included a control. All concentrations were observed once every 24 hours for mortality and abnormal effects such as surfacing, clumping of the daphnids together and daphnids lying on the bottom of test chambers.

The UC 54012 25WP (Lot #8-PLP-54) sample was received on July 23, 1986 as a tan powder and was stored at room temperature in the dark. Sample purity was 25.49%. Test concentrations were corrected for sample purity. All standard weights and dilutions can be found in the Appendix. Deionized water was used in the preparation of all working stock solutions.

The 24- and 48-hour LC_{50} values and corresponding 95-percent confidence limits were determined by an LC_{50} computer program developed by Stephan et al. (4). This program calculated the LC_{50} statistic and its 95-percent confidence limits using the binomial, moving average angle and probit methods because no one method is appropriate for all possible sets of data. The method of calculation selected was that which gave the narrowest confidence limits for each separate analysis.

RESULTS

Table 2 presents the predicted LC₅₀ values and 95-percent confidence intervals for UC 54012 25WP. The 24- and 48-hour LC₅₀ values for UC 54012 25WP were 0.99 and 0.26 mg/l. All results were based on the nominal concentrations of 0.10, 0.18, 0.32, 0.56, 1.0, 1.8 and 32 µg/l. The no-effect concentration based on the lack of mortality and abnormal effects was 0.10 µg/l after 48 hours. The abnormal effects of mortality, quiescence, surfacing, erratic locomotion and/or daphnids lying on the bottom of test vessels were observed in the 0.18, 0.32, 0.56, 1.0, 1.8 and 32 µg/l test concentrations.

Table 3 presents the mortality rate and water quality parameters measured during the test. The dissolved oxygen concentrations ranged between 8.4 and 8.6 mg/l. These values represented 91 and 93-percent saturation at 20°C, respectively, and were considered adequate for testing (1). The pH values of the treated chambers were consistent with the control and ranged from 8.1 to 8.2.

The study was conducted following the intent of the Good Laboratory Practice Regulations (5) and the final report was reviewed by Analytical Bio-Chemistry Laboratories' Quality Assurance Unit. All original raw data were provided to Union Carbide Agricultural Products Company, Inc., with a copy retained at Analytical Bio-Chemistry Laboratories.

TABLE 1: Chemical Characteristics of Well Water Used by ABC's Aquatic Toxicology Division.

Parameters	Concentration
Temperature	15-20°C ^b
Dissolved Oxygen ^a	9.2-10.1 ppm ^b
pH	7.8-8.3 ^b
Hardness (CaCO ₃)	225-275 ppm ^b
Alkalinity (CaCO ₃)	325-375 ppm ^b
Conductivity	700 µmhos/cm
NO ₃ -N	0.58 ppm
NO ₃ -NO ₂ -N	0.69 ppm
PO ₄ -P	<0.50 ppm
Aluminum	<20 ppb
Cadmium	<3 ppb
Chromium	<5 ppb
Cobalt	<5 ppb
Copper	<5 ppb
Iron	<5 ppb
Lead	<20 ppb
Nickel	<10 ppb
Silver	<5 ppb
Zinc	<1 ppb
Measured organophosphorus pesticides	<0.10 ppb
Measured organochlorine pesticides plus PCB's	<0.50 ppb

^aAfter aeration.

^bRepresents seasonal variation, with the monthly range not exceeding 10%.

Sample dates: Trace elements = May 12, 1986, organophosphate and organochlorine analyses = May 12, 1986.

TABLE 2
Acute Toxicity of UC 54012 25WP
to Daphnia magna^a

Compound	LC ₅₀ (µg/l)	
	24 hours	48 hours
UC 54012 25WP	0.99 ⁽²⁾ (0.75-1.3) ^b	0.26 ⁽²⁾ (0.21-0.31) ^b

^aBioassay conducted at 20°C (±2.0).

^b95% confidence limits.

The 48-hour no-effect concentration was 0.10 µg/l, based on the lack of mortality and abnormal effects.

All values were rounded to two significant figures following ABC S.O.P. #8.7.

LC₅₀ calculated using:

- (1) Binomial Method
- (2) Moving Average Method
- (3) Probit Method

TABLE 3
Mortality Rates and Water Quality Measurements During the
Acute Toxicity Test of UC 54012 25WP to Daphnia magna

Nominal Concentration (µg/l)	Percent Mortality		Water Quality					
			0 hours			48 hours		
	24 hr	48 hr	Temp. °C	D.O. ^a mg/l	pH ^b	Temp. °C	D.O. ^a mg/l	pH ^b
Control	0	0	20	8.5	8.2	20	8.5	8.2
0.10	0	0				20	8.6	8.1
0.18	0	45						
0.32	0	35						
0.56	35	100				20	8.6	8.2
1.0	65	100						
1.8	75	100						
3.2	75	100				20	8.4	8.1

^aDissolved oxygen concentrations - Dissolved Oxygen System (YSI Model 54).

^bpH - pH Probe (Corning Model 476182) used with a Corning Model 125 pH and mV meter.

NOTE: Dissolved oxygen saturations at the test temperatures of 20°C is 9.2 mg/l.

LITERATURE CITED

- (1) Committee on Methods for Toxicity Tests with Aquatic Organisms. Methods of Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians. 1975. U.S. EPA, Ecol. Res. Ser. 660/3-75009.
- (2) American Public Health Association. 1980. Standard Methods for the Examination of Water and Wastewater. 15th ed. Washington, DC. 1134 p.
- (3) Pennak, R. W. 1978. Freshwater Invertebrates of the United States. John Wiley & Sons, New York, 2nd ed. 803 p.
- (4) Stephan, C. E., K. A. Busch, R. Smith, J. Burke and R. W. Andrews. 1978. A Computer Program for Calculating an LC₅₀. U. S. Environmental Protection Agency, Duluth, Minnesota, pre-publication manuscript, August, 1978.
- (5) (a) U.S. Food and Drug Administration. 1978. Nonclinical Laboratory Studies, Good Laboratory Practice Regulations (21 CFR, Part 58). Federal Register, Vol. 43, No. 247:59986-60025.
(b) U.S. Environmental Protection Agency. 1983. Pesticide Programs; Good Laboratory Practice Standards; Final Rule (40 CFR, Part 160). Federal Register, Vol. 48, No. 230:53946-53969.
(c) U.S. Environmental Protection Agency. 1983. Toxic Substances Control; Good Laboratory Practice Standards; Final Rule (40 CFR, Part 792). Federal Register, Vol. 48; No. 230:53922-53944.
(d) Organization for Economic Cooperation and Development. 1981. OECD Guidelines for Testing of Chemicals, Principles of Good Laboratory Practice Annex 2, C(81) 30(Final):7-28.

QUALITY ASSURANCE STATEMENT

Quality Assurance Statement for final report #34978 entitled, "Acute Toxicity of UC 54012 25WP to Daphnia magna," for Dr. Thomas L. Merriam, Union Carbide Agricultural Products Company, Inc.; Research Triangle Park, North Carolina.

In accordance with ABC Laboratories' intent that all studies conducted at our facilities are designed and function in conformance with good laboratory practice regulations and the protocols for individual laboratory studies, an inspection of the final report for UC 54012 25WP was conducted and found to be in acceptable form by a member of our Quality Assurance Unit. A procedure audit was conducted on August 14, 1986. A final inspection of all data and records on August 25, 1986, indicates that the report submitted to you is an accurate reflection of the study as it was conducted by ABC Laboratories.

Should you have any questions relating to the information provided in this statement or the function of our Quality Assurance Unit, please contact the Quality Assurance Unit at your convenience.

Phillip M. Buckler 8/28/86
Phillip M. Buckler Date
Quality Assurance Supervisor

STUDY COMPLIANCE STATEMENT


Study Compliance Statement for ABC report #34978 entitled, "Acute Toxicity of UC 54012 25WP to Daphnia magna," for Dr. Thomas L. Merriam, Union Carbide Agricultural Products Company, Inc.; Research Triangle Park, North Carolina.

In accordance with ABC Laboratories' intent that all aquatic toxicity tests conducted by our facility follow good laboratory practices, ABC's study director for the above test herein confirms that the study was conducted in compliance with the U.S. E.P.A. Good Laboratory Practice Standards; Pesticide Programs (40 CFR 160).

All original raw data were sent to Union Carbide Agricultural Products Company, Inc., with a copy retained at Analytical Bio-Chemistry Laboratories.



Alan D. Forbis
ABC Study Director



Date



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

William C. Kuryla, Ph.D.
Associate Director, Product Safety
Union Carbide Corporation
39 Old Ridgebury Road
Danbury, Connecticut 06817-0001

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 10 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

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Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan

Terry R. O'Bryan
Risk Analysis Branch

Enclosure

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0503 INFO REQUESTED (VOL. ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)
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(0678) CAP NOTICESUB. DATE: 10/07/92 OTS DATE: 10/14/92 CSRAD DATE: 02/08/95

CHEMICAL NAME:

VC 54012 25WP

CAS#

35367-38-5

.11

VOLUNTARY ACTIONS:

(0401) NO ACTION RECOMMENDED
0402 STUDIES PLANNED/IN PROGRESS
0403 NOTIFICATION OF WORK IN PROGRESS
0404 LABEL/MSDS CHANGES
0405 PROCESS/ANALYSIS CHANGES
0406 APP/USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

INFORMATION TYPE:		P F C	INFORMATION TYPE:		P F C	INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04	0216	EPICLIN	01 02 04	0241	IMMUNO (ANIMAL)	01 02 04
0202	ONCO (ANIMAL)	01 02 04	0217	HUMAN EXPOS (PROD CONTAM)	01 02 04	0242	IMMUNO (HUMAN)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04	0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243	CHEM/PHYS PROP	01 02 04
0204	MUTA (IN VITRO)	01 02 04	0219	HUMAN EXPOS (MONITORING)	01 02 04	0244	CLASTO (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04	0220	ECO/AQUA TOX	01 02 04	0245	CLASTO (ANIMAL)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04	0221	ENV. OCCURRENCE/FATE	01 02 04	0246	CLASTO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04	0222	EMER INCI OF ENV CONTAM	01 02 04	0247	DNA DAM/REPAIR	01 02 04
0208	NEURO (HUMAN)	01 02 04	0223	RESPONSE REQUEST DELAY	01 02 04	0248	PROD/USE/PROC	01 02 04
0209	NEURO (ANIMAL)	01 02 04	0224	PROD/COMP/CHEM ID	01 02 04	0251	MSDS	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04	0225	REPORTING RATIONALE	01 02 04	0259	OTHER	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04	0226	CONFIDENTIAL	01 02 04			
0212	ACUTE TOX. (ANIMAL)	01 02 04	0227	ALLERG (HUMAN)	01 02 04			
0213	SUB ACUTE TOX (ANIMAL)	01 02 04	0228	ALLERG (ANIMAL)	01 02 04			
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04	0229	METAB/PHARMACO (ANIMAL)	01 02 04			
0215	CHRONIC TOX (ANIMAL)	01 02 04	0240	METAB/PHARMACO (HUMAN)	01 02 04			

TRIAGE DATA: NON-CBI INVENTORY

YES

ONGOING REVIEW

YES (DROP/REFER)

SPECIES

Daphnia Mayr

TOXICOLOGICAL CONCERN:

USE:

PRODUCTION:

CAS SR

NO

NO (CONTINUE)

MED

IN TRIAGE

REPLY

HIGH

1092-12045